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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/805,449	03/13/2001	Fu-Tong Liu	051501/027 8726	9750

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EXAMINER

LANDSMAN, ROBERT S

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 08/11/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/805,449

Applicant(s)

LIU ET AL.

Examin r

Robert Landsman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 14-47 is/are pending in the application.
- 4a) Of the above claim(s) 14-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 36-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. Formal Matters

- A. Amendment B, filed 5/22/03, has been entered into the record.
- B. Claims 1-35 were pending in the application. In Amendment B, filed 5/22/03, Applicants cancelled claim 13 and added claims 28-39. However, since claims 28-35 already exist, the newly added claims were renumbered under Rule 1.126 as new claims 36-47. Therefore, claims 1-47 are pending. Claims 14-35 are withdrawn as being drawn to non-elected subject matter. Therefore, claims 1-12 and 36-47 are the subject of this Office Action.
- C. Regarding the amendments to the claims, Applicants cite numerous pages to support their amendments. However, the pages Applicants have cited do not necessarily correspond to the actual pages of the specification. However, it is clear from the specification, Figures and original claims that the amendments do not add any new matter.
- D. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Specification

- A. The objection to the specification has been overcome in view of Applicants' amendment to add a brief description of Figure 12 to the Brief Description of the Drawings section in the specification. Applicants state that Figure 12 is discussed on page 35. However, it is discussed in Example 9 on page 37. This observation is stated only to maintain the clarity of the record.
- B. The objection to the title has been overcome in view of Applicants' amendment which more clearly indicates the invention to which the claims are directed.

3. Claim Rejections - 35 USC § 112, first paragraph – written description

- A. The rejection of claims 1-13 under 35 USC 112, first paragraph, has been withdrawn in view of Applicants' arguments. Based on Exhibits A-C, most strongly, Exhibit A, which demonstrate the structure and function of galectins 1-4, the Examiner agrees that Applicants have adequately described the genus of galectin-3 molecules and that the artisan would know how to identify a galectin-3 molecule. It is clearly

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demonstrated, for example in Figure 1 of Exhibit A, that galectin-3, unlike the other galectins, has a short N-terminal domain and an intervening proline, glycine and tyrosine-rich domain wherein the tyrosine-rich domain comprises PGAYPG(X)₁₋₄.

B. Claims 1-12 and 36-47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These are genus claims. The claims recite either inhibiting or stimulating cell migration by using varying amounts of galectin-3, or various binding polypeptides. However, in response to a rejection under 35 USC 112, second paragraph, Applicants have argued that inactive galectin-3 proteins can be made which can bind to the galectin-3 receptor, but which do not modulate cell migration. Similarly, Applicants argue that antibodies can be made which can lead to the formation of galectin oligomers. However, Applicants have not provided adequate written description of these proteins/antibodies. Inactive galectin-3 proteins would have one or more amino acid substitutions, deletions, insertions and/or additions to the wild-type protein and Applicants have not disclosed which residues could be altered to allow for binding of galectin-3 to the receptor, but wherein said receptor does not cause migration.

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. The specification and claims do not provide any guidance as to what changes should be made. Structural features that could distinguish compounds in the genus from others in the protein and antibody class are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, "inactive galectins" or "antibodies which produce galectin oligomers" alone are insufficient to describe the genus. One of skill in the art would reasonable conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus at the time the invention was made.

4. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement

A. Claims 5, 6 and 40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods for modulating migration of cells expressing a galectin-3 receptor by using galectin-3, N- or C-terminal subsequences thereof, as well as galectin binding polypeptides and galectin-3 receptor-binding polypeptides (e.g. antibodies), does not reasonably provide enablement for the use of any and all “subsequences” or “fragments” of galectin-3. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

First, the breadth of the claims is excessive with regard to Applicants claiming methods for modulating migration of cells expressing a galectin-3 receptor by using any and all “**subsequences**” or any and all “**fragments**” of galectin-3. Applicants have only provided guidance and working examples of the use of the full-length galectin-3 protein (e.g. Figures 1, 3 and 4), N- or C-terminal subsequences thereof (Figure 5; page 16, lines 16-19), as well as galectin binding polypeptides and galectin-3 receptor-binding polypeptides (e.g. Figure 2). Galectin-3 itself is approximately 250 amino acids in length and Applicants have not provided any guidance or working examples of the use of any and all “subsequences” or “fragments” of galectin-3, other than certain N- or C-terminal subsequences, which can be used to modulate the migration of galectin-3 receptor-expressing cells. These “subsequences” and “fragments” could have potentially hundreds of amino acid residues deleted and Applicants have provided only minimal guidance and working examples (e.g. C-terminal subsequence) as to which residues would need to be maintained in the protein in order to maintain the migration-modulating ability of the full-length galectin-3 protein, nor would it be predictable to one of ordinary skill in the art which residues would be able to be deleted and which would need to be maintained in order to maintain this desired activity.

Therefore, in summary, the breadth of the claims is excessive with regard to Applicants claiming methods for modulating migration of cells expressing a galectin-3 receptor by using any and all “subsequences” or any and all “fragments” of galectin-3. Furthermore, Applicants have only provided minimal guidance and working examples of “subsequences” and “fragments” of galectin-3 which can be used to modulate the migration of cells expressing a galectin-3 receptor. Furthermore, Applicants have

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provided only minimal guidance and working examples (e.g. C-terminal subsequence) as to which residues would need to be maintained in the protein in order to maintain the migration-modulating ability of the full-length galectin-3 protein. These reasons, along with the unpredictability for an artisan to identify which residues are required for the cell migration effect of galectin-3, leads the Examiner to hold that undue experimentation is required to practice the invention as claimed.

B. Claims 1-12 and 36-47 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods for stimulating migration of cells expressing a galectin-3 receptor by using galectin-3, N- or C-terminal subsequences thereof, as well as inhibiting migration using galectin binding polypeptides and galectin-3 receptor-binding polypeptides (e.g. antibodies), does not reasonably provide enablement for the use of inactive galectin-3 proteins or antibodies which oligomerize galectin-3 in order to stimulate migration. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The breadth of the claims is excessive with regard to Applicants claiming methods of stimulating migration of cells expressing a galectin-3 receptor by using inactive galectin-3 proteins, or antibodies which oligomerize galectin-3. Applicants have provided no guidance or working examples of these molecules. Applicants have not identified the critical residues which would be required in order to maintain the binding characteristics of galectin-3 while altering its migration ability, nor would it be predictable to the artisan how to make such a protein. Similarly, it would not be predictable to the artisan how to make an antibody which will allow for the oligomerization of galectin-3 proteins. For these reasons, the Examiner holds that undue experimentation would be required to practice the invention as claimed.

5. Claim Rejections - 35 USC § 112, second paragraph

A. The rejection of claim 5 under 35 USC 112, second paragraph, regarding “N- and C-terminal subsequences of galctin-3” has been withdrawn in view of Applicants’ amendment to the claims to remove reference to N- and C-terminal subsequences.

B. The rejection of claims 1-12 under 35 USC 112, second paragraph, regarding “the metes and bounds of galctin-3” has been withdrawn in view of Applicants’ arguments that one of ordinary skill in the art would clearly be able to identify a galectin-3 protein.

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C. The rejection of claims 3, 4 and 8-12 under 35 USC 112, second paragraph, has been withdrawn in view of Applicants' arguments regarding various compounds that can inhibit and stimulate migration.

6. Claim Rejections - 35 USC § 102

A. The rejection of claims 1-12 under 35 USC 102 has been withdrawn in view of Applicants' arguments that Hughes do not teach that galectin-3 can modulate cell migration.

7. Claim Rejections - 35 USC § 103

A. The rejection of claims 1-12 under 35 USC 103 has been withdrawn in view of Applicants' arguments that Hughes do not teach that galectin-3 can modulate cell migration.

8. Conclusion

A. No claim is allowable.

Advisory information


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
August 08, 2003


ROBERT LANDSMAN
PATENT EXAMINER